

FY2012 CDER Breakthrough Therapy Requests

(Jul 9, 2012 - Sep 31, 2012)

| Total Requests Received | Granted | Denied | Performance |
|------------------------------------|----------------|---------------|--------------------|
| 2 | 1 | 1 | 100%* |

* Percent where action was taken within 60 days of receipt of the request for breakthrough therapy designation.